CLAIMS

1. A drug/lipid complex comprising: at least one lipid species and a drug; the ratio of said lipid species to said drug being such that said complex has a positive charge excess of lipid to drug.

2. The complex of claim 1, wherein said drug is a nucleic acid.

3. The complex of claim 1, wherein said ratio of drug to lipid is from about 1 μg/0.1 nmol to about 1 μg/200 mmol.

4. The complex of claim 1, wherein said lipid species is a cationic lipid.

5. The complex of claim 4, wherein said complex further comprises a neutral phospholipid species.

6. The complex of claim 1, wherein said complex is purified from excess free drug and free lipid species.

7. A method for producing drug/lipid complexes having a positive charge excess of lipid to drug, said method comprising: mixing said drug with cationic liposomes in a drug to lipid ratio such that said drug/lipid complexes are formed.

8. The method of claim 7, wherein said ratio of drug to lipid mixed to form said complex is from about 1 μg/0.1 nmol to about 1 μg/200 nmol.

9. The method of claim 8, wherein said method further includes the step of purifying said complexes.

10. The method of claim 9, wherein said purifying step is centrifugation through a sucrose density gradient.

11. The method of claim 7, wherein the drug is nucleic acid and the liposomes are DC-Chol/DOPE liposomes.

12. A method for producing drug/lipid/polycation complexes having a positive charge excess of lipid and polycation to drug, said method comprising: mixing said drug with cationic liposomes and at least one polycation in a ratio of drug to lipid to polycation such that said complexes are formed.

13. The method of claim 12, wherein said polycation is present at from about 0.01 μg/0.1 nmol to about 1 μg/200 nmol.

14. The method of claim 12, wherein said polycation is present at from about 0.01 μg to about 100 μg.

15. The method of claim 14, wherein the polycation is poly-L-lysine having a molecular weight of about 300 to about 200,000 daltons.

16. The method of claim 12, wherein the cationic liposome comprises a cationic lipid and a neutral phospholipid.

17. The method of claim 16, wherein the cationic lipid is DC-Chol.

18. The method of claim 17, wherein the neutral phospholipid is dioleoyl phosphatidylethanolamine.

19. The method of claim 18, wherein the drug is nucleic acid.

20. The method of claims 7 or 12, wherein said complex has an average diameter less than 300 nm.

21. The method of claim 20, wherein the average diameter of said formulation remains substantially unchanged for up to one year in storage.

22. A drug/lipid/polycationic polypeptide complex comprising drug, at least one lipid species, and at least one polycationic polypeptide in a ratio such that said complex has a positive charge excess of lipid and polycationic polypeptide to drug.

23. The complex of claim 22, wherein said polycationic polypeptide has an amino acid composition in which arginine residues constitute greater than 30% of the amino acid residues of the polypeptide and lysine residues constitute less than about 5% of the amino acid residues of the polypeptide.

24. The complex of claim 23, wherein said drug is a nucleic acid.

25. The complex of claim 24, wherein said complex has a diameter of less than about 400 nm.

26. The complex of claim 24, wherein said complex has a drug/cationic peptide ratio between about 1:0.01 and 1:100.

27. The complex of claim 24, wherein said polypeptide from about 20 to about 100 amino acids in length.

28. The complex of claim 27, wherein the serine, threonine and glycine residues constitute from about 10 to about 25% of the amino acid residues of the polycationic polypeptide.

29. A method for producing drug/lipid/polycationic polypeptide complexes, said method comprising mixing drug to lipid to polycationic polypeptide in a ratio of from about 1 μg/0.1 nmol/0.01 μg to about 1 μg/200 nmol/100 μg.

30. The method of claim 29, wherein said drug to lipid to polycationic polypeptide ratio is from about 1 μg/1 nmol/0.1 μg to about 1 μg/20 nmol/10 μg.

31. The method of claim 29, wherein the polycationic polypeptide has an amino acid composition in which the arginine residues constitute greater than about 30% of the amino acid residues of the polypeptide and the lysine residues constitute less than about 5% of the amino acid residues of the polypeptide.

32. The method of claim 31, wherein the drug is a nucleic acid molecule.

33. The method of claim 32, wherein the lipid species is a cationic liposome.

34. The method of claim 33, wherein said nucleic acid, said lipid species and said polycationic polypeptide are mixed in a ratio of about 1 μg of nucleic acid to about 1 nmol to about 10 nmol of lipid to about 1 μg to about 5.0 μg polycationic polypeptide.

35. The method of claim 34, wherein said polycationic polypeptide is from about 20 to about 100 amino acids in length.

36. The method of claim 35, wherein said nucleic acid molecule encodes a protein or peptide.

37. The method of claim 36, wherein the ratio of nucleic acid lipid/polycationic polypeptide is 1 μg nucleic acid/5-10 nmol lipid/1-2 μg polycationic polypeptide.

38. The method of claim 37, wherein the polycationic polypeptide is a protamine.

39. The method of claim 38, wherein the polycationic polypeptide is protamine sulfate USP.

40. A method for delivering drug to cells comprising: contacting said cells with the complex of claim 22.

41. The method of claim 40, wherein the drug to be delivered is a nucleic acid molecule which encodes a protein or peptide.

42. The method of claim 41, wherein said complex has a diameter of less than about 400 nm.

43. The method of claim 40, wherein the cells are contacted with the complex in vivo, said method comprising administering the complex to an animal or human in an amount effective to deliver the drug into the cells of the animal or the human.

44. The method of claim 41, wherein the cells are contacted with the complex in vivo, said method comprising administering the complex to an animal or human in an amount effective to deliver the drug into the cells of the animal or the human.

45. A polycationic polypeptide nucleic acid complex, comprising nucleic acid and at least one polycationic polypeptide in a ratio of about 1 μg nucleic acid to about 0.1 μg to about 10 μg of polycationic polypeptide.